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Anita L Meik	lejohn		WHITEMAN, BRIAN A		
Fish & Richard	ison				
225 Franklin S	treet		ART UNIT	PAPER NUMBER	
Boston, MA	02110-28	04	1635		

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/889,874	MORGAN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Brian Whiteman	1635				
The MAILING DATE of this communication appe Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period willing to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be timil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
 Responsive to communication(s) filed on 10/21 This action is FINAL. 2b) This Since this application is in condition for allowan closed in accordance with the practice under Extended 	action is non-final. ce except for formal matters, pro					
Disposition of Claims						
4) Claim(s) 53-69 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) 53-56 and 64 is/are allowed. 6) Claim(s) 57-63 and 65-69 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examiner	on from consideration. The election requirement. The epted or b) □ objected to by the leading of the leading of the drawing	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/8/05.	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other:					

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DETAILED ACTION

Final Rejection

Claims 53-69 are pending.

Applicant's traversal and the amendment to claims 57 and 66-69 filed on 10/21/05 is acknowledged and considered by the examiner. However, the listing of the claims was incorrect. A non-compliant letter was mailed on 12/12/05.

The listing of claims filed on 1/17/06 was again incorrect and another non-compliant letter was mailed on 2/17/06.

Paper filed on 3/3/06 provides a correct listing of the pending claims.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/8/05 was filed after the mailing date of the non-final rejection on 4/21/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 57-63 and 65-69, as best understood, are readable on a genus of isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEQ ID NO: 23, wherein the polypeptide is toxic to nematode, wherein the genus of isolated nucleic acid sequences is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of isolated nucleic molecules that encode a polypeptide with at least 85% identity to the polypeptide set forth in SEQ ID NO: 23 and is a nematode control agent. The specification further contemplates methods of producing the polypeptide. The applicants disclosed methods of assessing homology at the nucleic acid level by hybridization screening. More specifically, page 16 recites:

One common formula for calculating the stringency conditions required to achieve hybridization between two nucleic acid molecules of a specified sequence homology in a Laboratory Manual:

The Tm of a DNA duplex increases by 1-1.5°C with every 1% decrease in homology.

Thus, targets with greater than about 75% sequence identity would be observed using a

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hybridization temperature of 42°C. Such a sequence would be considered substantially homologous to the nucleic acid sequence of the present invention.

The applicants obtained three strains (C42, I73, H31) using an insect entrapment method. I73 and H31 belong to the species X. bovienii. All three species were determined to have an effective nematocide. I73 was cloned and DNA sequence analysis was performed on the clone. The final sequence of the clone is shown in Figure 2 (37,544 bps) and the corresponding protein sequences are present in Annex 1 (Annex 1 has 51 amino acid sequences). The applicants identified that two regions of the clone were involved in nematocidial activity, p13-1f (SEQ ID NO: 22) and p14-2f (SEQ ID NO: 23). The as-filed specification provides sufficient description of a species of an isolated nucleic sequence encoding SEQ ID NO: 23. However, there is no evidence of record that p14-2f had a known structural relationship to a genus of nematode control agent DNA sequences. Based upon the prior art and the difference between the nucleotide sequence of SEQ ID NO: 23 and SEQ ID NO: 22 there is expected to be variation among species of DNA sequences that encode nematode control agents. The specification does not describe which nucleotide(s) of the sequence that encodes SEQ ID NO: 23 or what amino acid(s) of SEQ ID NO: 23 are considered essential for the biological activity of a nematode control agent. In view of the above considerations one of skill in the art would not recognize that the specification sufficiently describes a genus of claimed nucleotide sequences because SEQ ID NO: 23 is not a representative species of the claimed genus of isolated nucleotide sequences. It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are

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essential for the genus of isolated nucleic acid sequences as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of isolated nucleic acid sequences that must exhibit the disclosed biological functions as contemplated by the claims.

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<u>Vas-Cath Inc. v Mhurkar,</u> 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purpose of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u>, See MPEP 2163).

With the exception of the nucleic acid sequence encoding SEQ ID NO: 23, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or the simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v Chugai Pharmaceutical Co.

Ltd., 18 USPQ 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification only provided the bovine sequence.

Finally, <u>University of California v. Eli Lilly and Co.</u>, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997): *In re Gosteli*, 872 F.2d 1008, 1012,

10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement 'by describing the invention, with all it claimed limitations, not that which make it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc. that set forth the claimed invention." *Lockwood*, 107F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmid and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Dir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. At 1170, 25 USPQ at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information, concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is not further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes; as the example does, does not necessarily describe the cDNA itself. No sequence information indication which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the nucleotide sequence encoding SEQ ID NO: 23, but not the full breadth of the claims (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus of nucleotide sequences encoding a nematode control agent peptide is highly variant.

Applicant's arguments filed 10/21/05 have been fully considered but they are not persuasive.

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In response to applicant's argument that present claim 57 meets the standards set forth in *Lilly* because the claimed nucleic acid molecule include limitation to homology of the amino acid sequence of the polypeptide encoded by the nucleic acid molecule to a specific polypeptide (SEQ ID NO: 23) and the function of the polypeptide encoded by the nucleic acid molecule (toxicity to nematodes), the argument is not found persuasive because the written description requirements on based on the guidelines set forth in MPEP 2163 and not the *Lilly* court case. In addition, a genus of nucleic acid molecules encoding a polypeptide having at least 85% identity to SEQ ID NO: 23 encompasses the full-length sequence of SEQ ID NO: 23 or any portion of SEQ ID NO: 23. While it is acknowledged that the skilled artisan could align a nucleic acid molecule encoding a polypeptide having at least 85% identity to SEQ ID NO: 23. In view of the lack of description provided by the specification for what amino acid(s) or nucleotide(s) are considered essential for the biological activity (toxic to nematodes), the skilled artisan could not envision whether or not the nucleic acid molecule also possess the desired biological activity.

In response to applicant's argument that in view of Ex Parte Sun (Appeal No. 2003-1993) it is clear that a single species combined with a functional assay can provide an adequate written description for a claim to a genus of nucleic molecules, the argument is not found persuasive because every case is decided on its own merits. (*See In re Giolito*, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976):

"We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others." That other patents have been issued, based on different facts, is not evidence that the examiner's decision in this case, on these facts, is in error.

Furthermore, applicants have written description for a functional assay for determining whether a nucleic acid molecule encodes a polypeptide that is toxic to a nematode, but not for the claimed genus of nucleic acid molecules. Thus, the skilled artisan would have to further experiment to have possession of the claimed genus.

In response to applicant's argument that the specification (page 36 and Figure 4H) identifies insertion point of tn265 as reducing the toxicity of p15-2f (SEQ ID NO: 23) towards nematodes, the argument is not found persuasive because the applicants are not sure if the gene, region of DNA or the blocking effect of the transposon in this position is important for activity. Thus, the skilled artisan would have to further experiment whether the transposon or the gene or region of DNA is important for activity.

Claims 57-63 and 65-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 23, does not reasonably provide enablement for an isolated nucleotide sequence encoding a polypeptide with up to 98% identity to SEQ ID NO: 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The invention lies in the field of producing a genus of isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEQ ID NO: 23 and using the isolated nucleic acid molecule for generating a toxic response in a nematode.

The as-filed specification does not provide sufficient guidance and/or factual evidence for one skilled in the art to make and/or use a genus of isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEQ ID NO: 23, wherein the polypeptide is toxic to nematode other than the sequence itself. The claims embrace a genus of isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEO ID NO: 23, wherein the polypeptide is toxic to nematode. The instant specification fails to provide guidance as to which (if any) of the amino acids may be changed while activity is retained. There are 1,673 amino acids in the polypeptide sequence set forth in SEQ ID NO: 23. The total number of 1,673 amino acid peptides is 4 x 10²¹⁷⁶. The number of single amino acid substitutions is 33,460. The number of two amino acid substitutions is over $5x10^8$. The teaching in the specification do not commensurate in scope with the claims because the breadth of the claims embrace a large number of possible sequences that differ from SEQ ID NO: 23 by substitution of up to 15% of its amino acids, which would be a substitution of up to 250 amino acids of SEQ ID NO: 23. To determine the number of possible amino acid sequences, N, with 250 substitutions, one skilled in the art would use the formula [(N=xⁿL!/n!(Ln)!), where x=19 (number of possible amino acids that could replace an amino acid at any one position in SEQ ID NO: 23), L=1673 (amino acid length of SEQ ID NO: 23), n=250,] or 3x10¹⁰⁸² possible sequences. This is a lower limit of the number of possible sequences because the claims also embrace insertions or deletions of amino acids in SEQ ID NO: 23 that the equation does not take into account. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function

of the biomolecule in many instances, albeit not in all cases. The instant specification does not provide sufficient guidance and/or factual evidence that it was routine to substitute or delete at least two nucleotides of a nucleotide sequence and determine which nucleotide sequences meet the functional limitation of the claims. The effects of these changes is largely unpredictable as to which ones have a significant effect versus not. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over polypeptides of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Baker et al., Science, 294:pages 93-96, 2001); Attwood, T (Science, vol. 290, no. 5491, pp. 471-473, 2000); Gerhold et al., (BioEssays, vol. 18, no. 12, pp. 973-981, 1996); Russell et al., Journal of Molecular Biology, vol. 244, pp 332-350, 1994); and Wells et al., Journal of Leukocyte Biology, vol. 61, no. 5, pp. 545-550, 1997). Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain activity, and the fact that the relationship of the sequence of a peptide and its tertiary structure (e.g. its activity) are not well understood and are not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), it would require an undue amount of experimentation for one skilled in the art in view of the prior art to arrive at other sequences that have at least 85% sequence identity to a polypeptide encoded by SEQ ID NO: 23 and still possess nematocidial activity. Since it would require undue experimentation to identify other polypeptides that have nematocidial activity, it certainly would

require undue experimentation to make their corresponding DNA, and therefore, the entire scope of the claimed invention.

In conclusion, the as-filed specification and claims coupled with the art of record, at the time the invention was made, only provide sufficient guidance and/or evidence to reasonably enable making and using an isolated nucleotide sequence encoding the polypeptide set forth in SEQ ID NO: 23, does not reasonably provide enablement for a genus of an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEQ ID NO: 23, wherein the polypeptide is toxic to nematode. One skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the In Re Wands Factors including the lack of guidance in the application's disclosure, the unpredictability of producing a genus of isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having an amino acid sequence that is at least 85% identical to SEQ ID NO: 23, wherein the polypeptide is toxic to nematode.

Applicant's arguments filed 10/21/05 have been fully considered but they are not persuasive.

The majority of applicant's arguments (pages 7-9) have already been addressed in the previous office action mailed on 4/21/05.

In response to applicant's argument that in view of Ex Parte Sun (Appeal No. 2003-1993) it is clear that a single species combined with a functional assay can provide an adequate written description for a claim to a genus of nucleic molecules, the argument is not found persuasive because every case is decided on its own merits. *See In re Giolito*.

In response to applicant's argument that the specification (page 36 and Figure 4H) identifies insertion point of tn26 as reducing the toxicity of p15-2f (SEQ ID NO: 23) towards nematodes and identifies a functionally important region of SEQ ID NO: 23, the argument is not found persuasive because the applicants are not sure if the gene, region of DNA or the blocking effect of the transposon in this position is important for activity. Furthermore, the argument is not found persuasive because the claimed nucleic acid molecules are directed to a polypeptide that is toxic to nematodes. The identification of an insertion point of tn26 by applicants would further require undue experimentation to determine what regions of SEQ ID NO: 23 are considered essential for being toxic to nematodes or if the blocking effect of the transposon is important for activity. The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

In re Vaeck, 947 F.2d 48, 496 & n.23. 30 USPQ2d 1438, 1445 &n23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel. 984 F.2d.1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification provide no more than a plan or invitation in view of the art of record exemplifying the unpredictability of predicting a polypeptide having a desired biological activity, for those skilled in the art to further experiment with a genus of nucleic acid molecules so as to provide a nucleic acid molecule encoding a polypeptide having 85% identity to SEQ ID NO: 23, wherein the polypeptide is toxic to nematodes, as intended by the as-filed specification at the time the invention was made.

See also <u>Genentech Inc. v. Novo Nordisk A/S</u>, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what nucleic acid(s) or amino acid(s) are required for a polypeptide having 85% identity to SEQ ID NO: 23 that is toxic to nematodes, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the guidance in the specification to practicing the full breadth of the claimed invention.

Therefore, the as-filed specification is not enabled for the full scope of the claimed invention.

Double Patenting

Applicant is advised that should claim 57 be found allowable, claim 60 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

Applicant's arguments, see page 10, filed 10/12/05, with respect to 112 second paragraph rejection have been fully considered and are persuasive. The rejection of claim 67(claim 66) has been withdrawn because of the amendment to the claim.

Applicant's arguments, see pages 10-11, filed 10/12/05, with respect to 102(b) have been fully considered and are persuasive. The rejection of claim 56 has been withdrawn.

Conclusion

Claims 53-56 and 64 are free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

Patent Examiner, Group 1635

BRIAN WHITEMAN PATENT EXAMINER